Onderzoek naar ruggenmergstimulatie voor de behandeling van diabetische neuropathische pijn, een evaluatie studie

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29505

Source
NTR

Brief title
SCSDNP2

Health condition

diabetes mellitus,

diabetic neuropathic pain,

spinal cord stimulation,

diabetische neuropathische pijn,

ruggenmergstimulatie

Sponsors and support

Primary sponsor: Medisch Spectrum Twente,
Enschede, the Netherlands
Source(s) of monetary or material Support: Medisch Spectrum Twente,
Enschede, the Netherlands

Intervention

Outcome measures

Primary outcome

Primary outcome measure is the change in neuropathic pain as measured by visual analogue scale (VAS) score after 6 months of SCS.

Secondary outcome

- evaluation of patient preference of stimulation settings,

- satisfaction with SCS treatment (PGIC),

- evaluation of the efficacy of SCS treatment in patients with diabetic neuropathic pain as measured by mean and median percent change in pain intensity at all visits,

Study description

Background summary

Two Randomised Clinical Trials have shown that in many patients refractory painful diabetic neuropathy can be treated effectively with Spinal Cord Stimulation (SCS). It has also been suggested that novel stimulation settings might be even more effective in this patient population than the standard tonic stimulation settings that have been used in the two RCTs. A validation study to confirm the effects of SCS in diabetic neuropathic pain and to evaluate the effects of burststimulation will be relevant.

The study is a prospective, double-blind validation study.

20 patients with refractory diabetic neuropathic pain will be included. They should be eligible for spinal cord stimulation and have VAS scores for pain > 5. All patients will have a trial stimulation period with an external SCS pulse generator. If the trial is successful (> 25% pain reduction) an SCS system will be implanted. - During the first 12 weeks, SCS settings are adjusted and evaluated by the patients. Settings include 3 weeks of tonic, high burst, low burst stimulation settings and SCS off, in random order. Principal investigator and patients will be blind for the stimulation setting. - After completion of the 6 months study treatment period, all patients will be followed in accordance with standard medical care.

Primary outcome measure is the change in neuropathic pain as measured by VAS score after 6 months of SCS.

Study objective

A study to validate the results from two RCTs that SCS is indeed capable of treating otherwise refractory diabetic neuropathic pain. In addition, we will evaluate the effects of burst stimulation settings in this patient group.

Study design

After baseline and implantation, patients will have study visits after 3,6,9, and 12 weeks and a final study visit at 6 months

Intervention

Implantation of spinal cord stimulator and stuctured evaluation of various stimulation settings (tonic, high amplitude burst, low amplitude burst, placebo)

Contacts

Public
Medisch Spectrum Twente, Department of Neurosurgery,
P.O. Box 50000
C.C. Vos, de
Enschede 7500 KA
The Netherlands
+31 (0)53 4873532
Scientific
Medisch Spectrum Twente, Department of Neurosurgery,
P.O. Box 50000
C.C. Vos, de
Enschede 7500 KA
The Netherlands
+31 (0)53 4873532

Eligibility criteria

Inclusion criteria

- Peripheral neuropathic pain that exists for more than 6 months and is due to diabetes mellitus.

- Patient cannot be treated further otherwise according to patients’ medical specialist.

- The pain-sensation on a visual analogue scale is 5 or more

Exclusion criteria

- Age < 18 years.

- Psychological problems that requires treatment.

- Addiction (i.e. compulsory) to: drugs, alcohol, medication.

- Insufficient cooperation by patient (motivation, insight or communication).

- Coagulation irregularities/ Anti-coagulants.

- Immune compromised.

- Life expectancy less than 1 year.

- Pregnancy.

- Local infection at the site of the incision

- Implanted pacemaker, ICD or other neuromodulation system

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-06-2017
Enrollment:	20

Type:	Anticipated

Ethics review

Positive opinion
Date: 14-09-2017

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45247
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6515
NTR-old	NTR6704
CCMO	NL60465.044.17
OMON	NL-OMON45247

Study results